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EXAMINER

MCCORMICK, MELENIE LEE

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1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,107	Applicant(s) PONNAPALLI ET AL.	
	Examiner MELENIE MCCORMICK	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) 12, 13 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, and 9-11, 14 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's remarks with claim amendments submitted 28 March 2008 have been received and considered.

Claims 6 and 8 have been cancelled.

Claims 9-20 have been added.

Claims 1-5, 7, 9-20 are pending

Claims 12-13 and 15-19 have been withdrawn.

Claims 1-5, 7, 9-11, 14 and 20 are presented for examination on the merits.

Elections/Restrictions

Claims 12-13 and 15-19 appear to patentably distinct from the invention originally claimed. Claims 12-13 and 15-19, although dependent upon claim 1 appear to change the invention of claim 1 rather than further limit the invention of claim 1. These claims are distinct from claim 1 and the claims which originally depended from claim 1 because they appear to be drawn to different methods which have materially different designs. For example, claim 12 appears to be directed to a method of screening fruits, which contains steps that are not used in the method of claim 1. In addition, claim 13 is directed to a method of extracting furanocoumarins selectively with different chlorinated solvents. This appears to be a method of screening different solvents, which is not claimed in claim 1. In addition, claims 16-19 are directed to direct extraction with EDC/DCM and by using dry processes, which are not used in extraction method

disclosed in claim 1. These methods are therefore distinct from the method of claim 1 because they require different steps than the method of claim 1 and do not appear to require the method of claim 1, even though they are dependent upon claim 1.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-13 and 15-19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Rejections

The previous claim objection to claims 1-3 and 7 has been overcome by the claim amendments. Claim 6 has been cancelled so the claim objection is moot.

The previous rejection under 35 U.S.C has been withdrawn in view of the claim amendments to claims 1, 2, 4, and 7 which more clearly describe the claimed subject matter and the cancellation of claim 8.

Maintained Rejections/Objections

Claim Objections

Claims 4-5 stand objected to because they end with a semicolon. All claims must end in a period.

New Rejections

Claim Objections

Claims 1, 10-11 are objected to because of the following informalities:

In claim 1 at step c, 'imperatorin in halogenated solvent and obtain a miscella' should be amended so that it reads 'imperatorin to halogenated solvent to obtain a miscella'. Also in claim 1, at step g, 'phytosterols' is misspelled. Also in step g, it is suggested that 'pure imperatorin' be amended to read 'pure imperatorin fractions;'.

In claims 10-11, the ratios should be represented with colons, not periods. For example, claim 10 should read '1:3 to 1:6' In claim 12, there should be a space between 'claim' and '1' in line 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 14 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, the phrase 'is in the range ratio of 1:4 to 1:6' is confusing and indefinite. It is not clear what is meant by this phrase. Is this phrase referring to the ration

Claim 14 is indefinite in confusing because it is not known what is meant by 'bulkiness'.

Claim 20 recites 'mature fruits', 'immature fruits' and 'ripe fruits' in line 2. . There is insufficient antecedent basis for these limitations in the claim. It is also not clear at what step in the process of claim 1 the 'extraction in a Soxhlet apparatus for 6-12 hours with ethylenedichloride' occurs. This phrase also lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 5, 7, and 9-11, 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saha et al. (1957) in view of Bastnet et al. (2001) and in view of Bizhanova et al. (1977).

Although unclear (see rejection under 35 U.S.C. 112, second paragraph above), the term 'bulkiness' has been interpreted to mean volume.

Saha et al. beneficially teach a method of isolating imperatorin which comprises the steps of extracting fruit pulp of *Angle marmelos* with alcohol under reduced pressure (which would concentrate the alcoholic extract), and then freeing the extracted pulp from alcohol under reduced pressure and soxhletting with benzene (the step of freeing the extract from alcohol and then extracting in another solvent would to 'partition' the extract from the alcohol to the benzene, which would necessarily reduce the volume of the alcohol extract). Saha et al. further teaches that the extract is then dried over anhydrous sodium sulfate and concentrated (thus the solvent would be removed). Saha further teaches that the extract is then crystallized in ethanol (see e.g. 229 –isolation of Alloimperatorin). Saha et al also teaches that the mother liquid left over after the crystallization is then chromatographed over a column of alumina and then eluted with benzene and crystallized with petroleum ether. It is further disclosed that this elution and crystallization is repeated and multiple fractions are collected. (see e.g. page 229- Isolation of Imperatorin).

Saha et al. do not explicitly teach that a halogenated solvent is used or that a silica gel column is used.

Bastnet et al. beneficially teach that imperatorin is found in the chloroform soluble fraction of a methanolic extract of a plant (see e.g. abstract).

Bizhanova et al. beneficially teach that imperatorin can be isolated after alcoholic extraction using a silica gel column (see .g. English Abstract).

It would have been obvious to one of ordinary skill in the art to optionally select another non-polar solvent besides the benzene used by Saha in the method of isolating imperatorin taught by Saha. A person of ordinary skill in the art at the time the claimed invention was made would have had a reasonable expectation of success in substituting chloroform for the benzene taught by Saha because Bastnet discloses that imperatorin is soluble in chloroform. Thus, a person of ordinary skill in the art would have a reasonable expectation of success in isolating imperatorin using chloroform. A person of ordinary skill in the art would have also had a reasonable expectation of success in using silica gel column chromatography instead of alumina since Bizhanova et al. also teach teaches that after an alcoholic extraction, imperatorin can be separated using silica gel. The particular mesh size would be routine experimentation since the compound being isolated (imperatorin) is known. Although the filtration step instantly claimed in steps e and f of claim 1 is not explicitly taught by Saha et al., the removal of the crystals from the 'mother liquid' would suggest to one of ordinary skill in the art that filtrations must have taken place. Although the particular type of fruit pulp (i.e. immature/mature or dry/fresh) is not explicitly taught, a person of ordinary skill in the art would have a reasonable expectation of success in using what is readily available, which would inevitably be one of the instantly claimed types of *Angle marmelos*. It is also considered routine experimentation to optimize the time which is spent on extraction and the particular pulp to solvent ratio depending upon the yield of imperatorin which is desired. Although the particular yield of imperatorin after the soxhletting step taught by Saha is not explicitly taught and the amount of time spent

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soxhletting is not taught, a person of ordinary skill in the art would have a reasonable expectation of success in optionally adjusting the amount of time spent during any step in the extraction process in order to improve the yield of the desired product.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655

/Patricia Leith/

Primary Examiner, Art Unit 1655